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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,821	10/07/2003	Anant V. Hegde	PAVA-001/01US	6623
23419	7590	05/03/2006	EXAMINER	
COOLEY GODWARD, LLP			KRAMER, NICOLE R	
3000 EL CAMINO REAL			ART UNIT	PAPER NUMBER
5 PALO ALTO SQUARE				
PALO ALTO, CA 94306			3762	

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/681,821	HEGDE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Nicole R. Kramer	3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 October 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-232 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-232 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### ***Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-39 and 122-170, drawn to a device including two layers forming a cavity therebetween in which the second layer has a stiffness greater than the first layer, classified in class 600, subclass 618.
  - II. Claims 40-82, drawn to drawn to a device including two layers forming a cavity therebetween in which a reinforcement layer is coupled to the second layer, classified in class 600, subclass 618.
  - III. Claims 83-103, drawn to a device including two layers forming a cavity therebetween in which a third layer is disposed between the expanding/compliant layer and the outer surface of the vasculature, classified in class 600, subclass 618.
  - IV. Claims 104-121, drawn to a device including two layers forming a cavity therebetween in which a portion of the second layer extends past the first layer, classified in class 600, subclass 618.
  - V. Claims 171-210, drawn to methods of augmenting blood flow, classified in class 600, subclass 617.
  - VI. Claims 211-232, drawn to a system of interconnected cuffs, classified in class 600, subclass 618.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed (i.e., claim 40) does not require the particulars of the subcombination as claimed (i.e., claim 1) because the device of claim 40 does not require that the second layer have a greater stiffness than the first layer. The subcombination has separate utility such as a vascular assist device not having a reinforcement element coupled to the second layer.
3. Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed (i.e., claim 83) does not require the particulars of the subcombination as claimed (i.e., claim 1) because the device of claim 83 does not require that the second layer have a greater stiffness than the first layer. The subcombination has separate utility such as a vascular assist device not having a third layer disposed between the expanding/compliant layer and the outer surface of the vasculature.
4. Inventions I and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed

does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed (i.e., claim 104) does not require the particulars of the subcombination as claimed (i.e., claim 1) because the device of claim 104 does not require that the first layer be configured to be deformed in response to a change in the volume of the cavity. The subcombination has separate utility such as a vascular assist device not having a portion of the second layer extend past the first layer.

5. Inventions I and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process, such as being utilized as a passive restraint device which engages a blood vessel (i.e., no fluid is ported into the cavity).

6. Inventions I and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed (i.e., claim 211) does not require the particulars of the subcombination as claimed (i.e., claim 1) because the system does not require that the second layer have a greater stiffness than the first

layer. The subcombination has separate utility such as a singular vascular assist device (i.e., only one cuff is required to be utility).

7. Inventions II and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed (i.e., claim 83) does not require the particulars of the subcombination as claimed (i.e., claim 40) because the system does not require that a reinforcement layer coupled to the second layer. The subcombination has separate utility such as a vascular assist device not having a third layer disposed between the expanding/compliant layer and the outer surface of the vasculature.

8. Inventions II and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed (i.e., claim 40) does not require the particulars of the subcombination as claimed (i.e., claim 104) because the system does not require that the second layer have a greater stiffness than the first layer. The subcombination has separate utility such as a vascular assist device not having a portion of the second layer extend past the first layer.

9. Inventions II and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process, such as being utilized as a passive restraint device which engages a blood vessel (i.e., no fluid is ported into the cavity).

10. Inventions II and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed (i.e., claim 211) does not require the particulars of the subcombination as claimed (i.e., claim 1) because the system does not require a reinforcement element coupled to the second layer. The subcombination has separate utility such as a singular vascular assist device (i.e., only one cuff is required to be utility).

11. Inventions III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed (i.e., claim 83) does not require the particulars of the subcombination as claimed (i.e., claim 104) because the

system does not require that the second layer have a greater stiffness than the first layer. The subcombination has separate utility such as a vascular assist device not having a third layer disposed between the expanding/compliant layer and the outer surface of the vasculature.

12. Inventions III and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process, such as being utilized as a passive restraint device which engages a blood vessel (i.e., no fluid is ported into the cavity).

13. Inventions III and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed (i.e., claim 211) does not require the particulars of the subcombination as claimed (i.e., claim 83) because the system does not require a third layer disposed between the expanding/compliant layer and the outer surface of the vasculature. The subcombination has separate utility such as a singular vascular assist device (i.e., only one cuff is required to be utility).

14. Inventions IV and V are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be

practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process, such as being utilized as a passive restraint device which engages a blood vessel (i.e., no fluid is ported into the cavity).

15. Inventions IV and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed (i.e., claim 211) does not require the particulars of the subcombination as claimed (i.e., claim 104) because the system does not require that the second layer have a greater stiffness than the first layer, or that a portion of the second layer extend past the first layer. The subcombination has separate utility such as a singular vascular assist device (i.e., only one cuff is required to be utility).

16. Inventions V and VI are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process, such as being utilized as a passive restraint device which engages a blood vessel (i.e., no fluid is ported into the cavity).

17. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

18. A telephone call was made to Applicant's Representative, James Shay, on April 27, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole R. Kramer whose telephone number is 571-272-8792. The examiner can normally be reached on Monday through Friday, 8 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*NRK*  
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4/27/06

*G. M.*  
George Manuel  
Primary Examiner